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Proposed Maximum Residue Limit

PMRL2014-25

Flubendiamide

(publié aussi en français)

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing to establish Maximum Residue Limits (MRLs) for flubendiamide on various commodities to permit the import and sale of foods containing such residues.

Flubendiamide is an insecticide not currently registered for use in Canada.

The PMRA must determine the quantity of residues that are likely to remain in or on the imported food commodities when flubendiamide is used according to label directions in the exporting country, and that such residues will not be a concern to human health. This quantity is then legally established as a MRL on the corresponding imported commodity. A MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for flubendiamide is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs for flubendiamide are as follows:

Table 1 Proposed Maximum Residue Limits for Flubendiamide

| Common name | Residue definition | MRL (ppm) ¹ | Food commodity |
|---------------|---|------------------------|--|
| Flubendiamide | $N^2\text{-}[1,1\text{-dimethyl-2-(methylsulfonyl)ethyl}]\text{-}3\text{-iodo-}N^1\text{-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide}$ | 30 | Leafy <i>Brassica</i> greens (Crop subgroup 5B) |
| | | 15 | Spinach |
| | | 9.0 | Leafy vegetables (except <i>Brassica</i>) (Crop group 4) except spinach |
| | | 4.0 | Head and stem <i>Brassica</i> (Crop subgroup 5A) |

| Common name | Residue definition | MRL (ppm)¹ | Food commodity |
|--------------------|---------------------------|------------------------------|---|
| | | 2.0 | Stone fruits (Crop group 12-09), Small fruit vine climbing, except fuzzy kiwifruit (Crop subgroup 13-07F) |
| | | 0.8 | Pome fruits (Crop group 11-09), dried tomatoes |
| | | 0.4 | Fruiting vegetables (Crop group 8-09) |
| | | 0.2 | Cucurbit vegetables (Crop group 9) |
| | | 0.1 | Tree nuts (Crop group 14-11) |
| | | 0.03 | Field corn |
| | | 0.02 | Popcorn grain |
| | | 0.01 | Sweet corn kernels plus cob with husks removed |

ppm = parts per million

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

Table 2 compares the MRLs proposed for flubendiamide in Canada with corresponding American tolerances and Codex MRLs.¹ American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

¹ The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Table 2 Comparison of Canadian Maximum Residue Limits, American Tolerances and Codex MRLs (where different)

| Food commodity | Canadian MRL (ppm) | American tolerance (ppm) | Codex MRL (ppm) |
|--|--|--|---|
| Leafy vegetables (except <i>Brassica</i>) (Crop group 4) | 9 (Crop Group 4 - except spinach) 15 (spinach) | 11 (Vegetable, leafy, except <i>Brassica</i> , group 4) | 5 (Lettuce, head and celery) 7 (Lettuce, leaf) |
| Head and stem <i>Brassica</i> vegetables (Crop subgroup 5A) | 4.0 | 3.0 | 4 (<i>Brassica</i> (Cole or Cabbage) Vegetables, Head cabbage, Flowerhead <i>Brassicas</i>) |
| Leafy <i>Brassica</i> greens (Crop subgroup 5B) | 30 | 25 | Not established |
| Fruiting vegetables (Crop group 8-09) | 0.4 | 0.60 (Vegetable, fruiting, group 8) 0.3 (okra) | 2 (Tomato) 0.7 (Peppers) 7 (Peppers chili, dried) |
| Cucurbit vegetables (Crop group 9) | 0.2 | 0.20 | 0.2 (Fruiting vegetables, cucurbits) |
| Pome fruits (Crop group 11-09) | 0.8 | 1.5 (Fruit, pome, group 11) | 0.8 (Pome fruits) |
| Stone Fruits (Crop group 12-09) | 2.0 | 1.6 (Fruit, stone, group 12) | 2.0 (Stone fruits) |
| Tree nuts (Crop group 14-11) | 0.1 | 0.06 (Nut, tree, group 14) | 0.1 (Tree nuts) |
| Small fruit vine climbing except fuzzy kiwifruit (Crop subgroup 13-07F) | 2.0 | 1.4 | 2.0 (Grapes) |

| Food commodity | Canadian MRL (ppm) | American tolerance (ppm) | Codex MRL (ppm) |
|-----------------------|--|--|---|
| Corn | 0.03 (field corn) | 0.03 (Corn, field, grain) | 0.02 (Maize and sweet corn (corn-on-the-cob)) |
| | 0.02 (popcorn grain) | 0.02 (Corn, pop, grain) | |
| | 0.01 (sweet corn kernel + cob with husk removed) | 0.01 (Corn, sweet, kernel plus cob with husks removed) | |
| Dried tomatoes | 0.80 | Not established | Not established |

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for flubendiamide up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limits

Residue data for flubendiamide in various crops were submitted to support the MRLs on imported leafy vegetables, except *Brassica* (CG 4), head and stem *Brassica* vegetables (CSG5A), leafy *Brassica* greens (CSG 5B), fruiting vegetables (CG 8-09), cucurbit vegetables (CG 9), pome fruits (CG 11-09), stone fruits (CG 12-09), tree nuts (CG 14-11), grapes and corn. In addition, processing studies in treated grape, apple, tomato, plum and corn were reviewed to determine the potential for concentration of residues of flubendiamide into processed commodities.

Maximum Residue Limits

The recommendation for MRLs for flubendiamide was based on the residues observed in crops treated according to American label directions, and the guidance provided in the Organisation for Economic Co-operation and Development's MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL(s) for imported leafy vegetables except *Brassica* (CG 4), head and stem *Brassica* vegetables (CSG5A), leafy *Brassica* greens (CSG 5B), fruiting vegetables (CG 8-09), cucurbit vegetables (CG 9), pome fruits (CG 11-09), stone fruits (CG 12-09), tree nuts (CG 14-11), grapes, corn and dried tomatoes.

Table A1: Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits

| Commodity | Application method/ Total application rate (g a.i./ha) | Pre-Harvest Interval (days) | Residues (ppm) | | Experimental processing factor |
|------------------------------------|--|-----------------------------------|----------------|--------------------------------------|-----------------------------------|
| | | | Min | Max | |
| Head lettuce (with wrapper leaves) | Foliar/250-258 | 1 | 0.100 | 1.16 | -- |
| Leaf lettuce | Foliar/246-252 | 1 | 0.293 | 5.89 | -- |
| Celery | Foliar/250-253 | 1 | 0.410 | 2.62 | -- |
| Spinach | Foliar/250-255 | 1 | 2.37 | 6.72 | -- |
| Broccoli | Foliar/250-258 | 1 | 0.140 | 1.150 | -- |
| Cauliflower | Foliar/253-259 | 1 | 0.010 | 0.322 | -- |
| Cabbage (with wrapper leaves) | Foliar/252-255 | 1 | 0.133 | 2.180 | -- |
| Mustard Greens | Foliar/250-256 | 1 | 4.17 | 15.90 | -- |
| Tomato | Foliar/246-257 | 1 | <0.01 | 0.176 (HAFT ¹ = 0.155) | 5.1 (Dried tomato) |
| Bell pepper | Foliar/246-253 | 1 | 0.036 | 0.12 | -- |
| Non-bell pepper | Foliar/251-253 | 1 | 0.017 | 0.142 | -- |

| Commodity | Application method/ Total application rate (g a.i./ha) | Pre- Harvest Interval (days) | Residues (ppm) | | Experimental processing factor |
|----------------------|---|---|-----------------------|------------|---|
| | | | Min | Max | |
| Cucumber | Foliar/263-285 | 1 | <0.01 | 0.031 | -- |
| Muskmelon | Foliar/260-281 | 1 | <0.01 | 0.093 | -- |
| Squash | Foliar/262-275 | 1 | <0.01 | 0.043 | -- |
| Apple | Foliar/515-549 | 11-14 | 0.032 | 0.480 | -- |
| Pear | Foliar/517-531 | 13-14 | 0.039 | 0.590 | -- |
| Cherry | Foliar/414-426 | 7 | 0.142 | 1.003 | -- |
| Peach | Foliar/414-426 | 7 | 0.109 | 0.397 | -- |
| Plum | Foliar/414-426 | 7 | 0.011 | 0.501 | -- |
| Almond nutmeat | Foliar/416-424 | 14 | <0.01 | 0.055 | -- |
| Pecan nutmeat | Foliar/410-464 | 12-14 | <0.01 | 0.028 | -- |
| Field corn grain | Foliar/414-446 | 26-35 | <0.01 | 0.018 | -- |
| Sweet corn K+CWHR | Foliar/420-438 | 1-2 | <0.01 | <0.01 | -- |
| Grape | Foliar/416-429 | 7 | 0.116 | 0.806 | -- |

¹HAFT = Highest Average Field Trial

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of flubendiamide. Residues of flubendiamide in these imported crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.